K003824 p1/2

MAR - 8 2001

OmniSonics Medical Technologies
Ultrasonic Surgery System

02/16/01
PreMarket Notification

510K Summary of Safety and Effectiveness

1. Sponser Name

OmniSonics Medical Technologies, Inc.
66 Concord Street
Suite A
Wilmington, MA 01887
(978) 657-9980
Contact Individual: Doug Charland

2. Device Name

Propriety Name: Omnisonics Ultrasonic Aspiration Device
Common/Usual Name: Ultrasonic Aspiration Device
Classification Name: LFL

3. Identification of Predicate or Legally Marketed Device

The OmniSonics Ultrasonic Surgery System is a mechanical ultrasonic surgical aspirator which is substantially equivalent in intended use and function to its predecessor, the predicate Sonokinetics SONOTOME™ System (K990572). The Ultracision Device (K993054) has been cleared as a substitute for electro surgery, lasers and scalpels in abdominal, pediatric, gynecological and other endoscopic procedures.

4. Device Description

The Omnisonics Ultrasonic Surgery System contains three subsystems: ultrasonic energy, irrigation and aspiration. The Ultrasonic Surgery System uses a single patient contact titanium probe securely mounted on a reusable handpiece, to effect tissue removal. The generator provides an oscillating electrical signal that is converted into a mechanical vibration at the active end of the probe. The irrigation and the ultrasonic energy are activated by depressing a footswitch. The vibrating tip of the probe is then applied to the tissue or material to be worked on. The tissue, blood, saline and other debris is automatically aspirated at or around the tip and into a disposable vacuum canister. The flow of saline is maintained to reduce the temperature of the probe, to assist in the ultrasonic destruction of the tissue and to provide a means of irrigation to the surgical site.

5. Intended Use

The intended use of the OmniSonics Ultrasonic Surgery System is be the breakup and removal of soft tissues in Neurosurgery, GI and affiliated organ surgery, Urology, General surgery, Plastic and Reconstructive surgery, Orthopedic, GYN, Thoracic and ENT

6. Comparison of Technological Characteristics

The OmniSonics Ultrasonic Surgical System is the same device as the predicate Sonokinetics SONOTOME™ System with some modifications to the Generator/Control Module which improve the operation of the device, and one change in the indications for use.

The operating principle, as well as , system accessories and disposable components, of the OmniSonics Ultrasonic Surgical System are the same as the predicate Sonokinetics SONOTOME™ System (K990572). Differences exist in the Generator/Control Module in which changes were made to make the system easier to use in its intended environment. While the main function of the software remains the same, changes in the software were required to implement the increased functionality of the Generator/Control Module and its display.

7 Performance Testing

The OmniSonics Ultrasonic Surgical System complies with the following standards:

UL 2601	General Requirements for Safety
IEC 60601-1-2	Electro Magnetic Compatibility
IEC 529	Degrees of Protection Provided by Enclosures

FDA Software Guidance – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 2001

Mr. Doug Charland
Quality Assurance Director
OmniSonics Medical Technologies
66 Concorde Street, Suite A
Wilmington, Massachusetts 01887

Re: K003824
Trade Name: OmniSonics Ultrasonic Surgery System
Regulatory Class: Unclassified
Product Code: LFL
Dated: December 5, 2000
Received: December 11, 2000

Dear Mr. Charland:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K003824

Device Name: OmniSonics Ultrasonic Surgery System

Indications For Use:

The intended use of the OmniSonics Ultrasonic Surgery System is the breakup and removal of soft tissues in Neurosurgery, GI and affiliated organ surgery, Urology, General surgery, Plastic and Reconstructive surgery, Orthopedic, GYN and Thoracic.

(PLEASE DO NOT WRITE BELOW THE LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Miriam C Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003824